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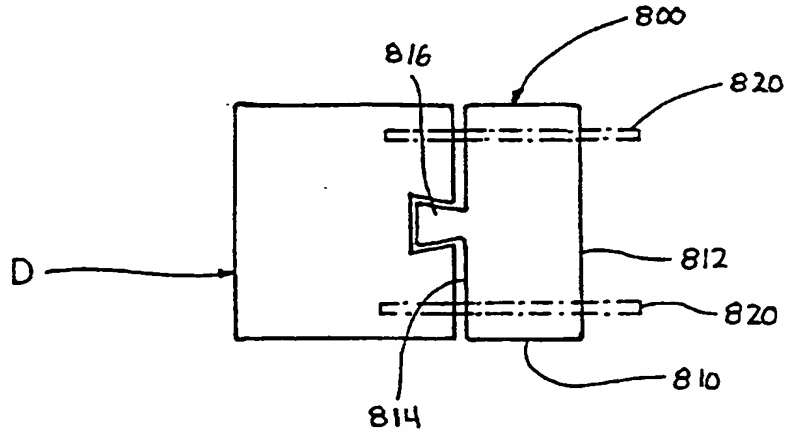
(54) Title: INTERVERTEBRAL IMPLANTS



(57) Abstract: A multipart intervertebral implant is provided which includes an implant portion and an implant extender portion. The implant portion and the implant extender portion can be fastened together using any known fastening means including pins, interlocking structure (e.g., dovetail, tongue and groove, etc.), adhesives, etc. The size of the implant extender portion can be selected during a surgical procedure to provide an implant suitable for a particular intervertebral receiving bed. An intervertebral implant is also provided which may be formed from a multiplicity of implant sections which are fastened together to provide an implant having a desired length. Implants having surface configurations which more closely correspond to the configuration of vertebral endplates are also provided.

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INTERVERTEBRAL IMPLANTS

This application claims priority from United States provisional application Serial No. 60/173,973, filed December 30, 1999, which is incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates generally to biocompatible implants and, more particularly, to intervertebral implants suitable for implantation into the lumbar, thoracic and/or cervical regions of the spine during a spinal fusion procedure.

2. Background of Related Art

Intervertebral implants for fusing together adjacent vertebrae of a spinal column are well known in the art. Such implants are formed in a variety of different shapes and sizes and are configured for insertion into receiving beds formed in the lumbar, thoracic and cervical regions of the spine. The implants may be formed from a variety of different biologically compatible materials including ceramics, polymers, human or animal bone, composites, etc. The implants may also be shaped to maintain the natural lordoses of the spine or to prevent the implant from backing out of an intervertebral receiving bed in which it will be implanted.

Examples of known implants are disclosed in U.S. Patent No. 4,877,020 to Vich and U.S. Patent No. 4,878,915 to Brantigan. Vich and Brantigan each disclose cylindrical implants having an outer helical thread formed thereabout. The Vich implant is formed from autogenic bone taken from the iliac crest of a patient. The Brantigan implant is formed of an inert metal such as stainless steel, cobalt-chromium-molybdenum alloys and titanium.

One problem associated with known implants is the difficulty in adapting an implant to meet the size requirements of a particular intervertebral receiving bed. For example, because anatomically all patients are different, the specific size of implant required for a surgical procedure will not be known to any certainty until a surgeon has prepared the intervertebral space for implantation. Thus, a surgeon must keep a variety of different size implants available for use or have means to alter the dimensions of the implant at his disposal.

Another problem associated with known implants constructed from bone is that the anatomical limitations of donor bone limit the size of the implant which can be formed from bone. As a result, bone having satisfactory strength characteristics may not be available for use as an implant because of size limitations

Finally, yet another problem associated with known implants is their inability to accurately maintain the natural lordoses of the spine. Because of the irregular shape of the vertebral endplates, wedge-shaped implants and cylindrical dowels are incapable of supporting adjacent vertebrae in their natural orientation without substantially altering the shape of the vertebral endplate(s).

Accordingly, a continuing need exists for an intervertebral implant whose size may be easily altered by a surgeon during a surgical procedure to meet the size requirements of a particular implant receiving bed and for an implant capable of maintaining the natural lordoses of the spine without substantially altering the shape of the vertebral endplates.

SUMMARY

In accordance with the present disclosure, intervertebral implants are provided which more precisely correspond in shape to the shape of the vertebral endplates. In one preferred embodiment, an implant is formed from a ring of material having a top surface and a bottom

surface. The top and/or bottom surfaces of the implant include a series of annular stepped surfaces which together define a convex configuration which closely corresponds to the concave shape of the vertebral endplates. In an alternate embodiment, the annular stepped surfaces on the top and/or bottom surfaces of the implant can be replaced by a single helical pathway.

In another preferred embodiment, a multipart intervertebral implant is provided which includes an implant portion and an implant extender portion. The implant portion and the implant extender portion can be fastened together using any known fastening means including pins, interlocking structure (e.g., dovetail, tongue and groove, etc.), adhesives, etc. The size of the implant extender portion can be selected during a surgical procedure to provide an implant suitable for a particular intervertebral receiving bed.

In yet another preferred embodiment, an intervertebral implant may be formed from a multiplicity of implant sections which are fastened together to provide an implant having a desired length. These implant sections and the implants described above can be formed of any biocompatible material including bone.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed intervertebral implants are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one preferred embodiment of the presently disclosed intervertebral implant;

FIG. 2 is a top view of the intervertebral implant shown in FIG. 1;

FIG. 3 is a side view from a first side of the intervertebral implant shown in FIG. 1;

FIG. 4 is a top perspective view of the intervertebral implant shown in FIG. 1;

FIG. 5 is a side view from the other side of the intervertebral implant shown in FIG. 1;

FIG. 6 is a perspective view of another preferred embodiment of the presently disclosed intervertebral implant;

FIG. 6A is a perspective view of another preferred embodiment of the presently disclosed intervertebral implant;

FIG. 7 is a top view of the intervertebral implant shown in FIG. 6;

FIG. 8 is a side view of the intervertebral implant shown in FIG. 6;

FIG. 9 is a top perspective view of the intervertebral implant shown in FIG. 6;

FIG. 10 is another side view of the intervertebral implant shown in FIG. 6;

FIG. 11 is an elevational view of the intervertebral implant shown in FIG. 6 positioned between adjacent vertebrae;

FIG. 12 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

FIG. 13 is a side view of the intervertebral implant shown in FIG. 12;

FIG. 14 is a top view of the intervertebral implant shown in FIG. 12;

FIG. 15 is a rear end view of the intervertebral implant shown in FIG. 12;

FIG. 16 is a perspective view of yet another embodiment of the presently disclosed intervertebral implant;

FIG. 17 is a side view of the intervertebral implant shown in FIG. 16;

FIG. 18 is a top view of the intervertebral implant shown in FIG. 16;

FIG. 19 is a rear end view of the intervertebral implant shown in FIG. 16;

FIG. 20 is a perspective view of yet another embodiment of the presently disclosed intervertebral implant.

FIG. 21 is a side view of the intervertebral implant shown in FIG. 20;

FIG. 22 is a top view of the intervertebral implant shown in FIG. 20;

FIG. 23 is a rear end view of the intervertebral implant shown in FIG. 20;

FIG. 24 is a top view of yet another embodiment of the presently disclosed intervertebral implant;

FIG. 25 is yet another embodiment of the presently disclosed intervertebral implant;

FIG. 26 is a side view of the intervertebral implant shown in FIG. 25 positioned between adjacent vertebrae;

FIG. 27 is a side view of the presently disclosed intervertebral implant and implant extender positioned between adjacent vertebrae with the implant extender positioned adjacent the leading end of the intervertebral implant;

FIG. 28 is a side view of the intervertebral implant and implant extender shown in FIG. 27 positioned between adjacent vertebrae with the implant extender positioned adjacent the trailing end of the intervertebral implant;

FIG. 29 is a side view of an alternate embodiment of the presently disclosed intervertebral implant and implant extender in an interlocked configuration;

FIG. 30 is a side view of the intervertebral implant and implant extender shown in FIG. 29 in a partially assembled configuration; and

FIG. 31 is a perspective view of yet another embodiment of the presently disclosed intervertebral implant.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS:

Preferred embodiments of the presently disclosed intervertebral implant and implant extender will now be described in detail with reference to the drawings in which like reference

numerals designate identical or corresponding elements in each of the several views.

FIGS. 1-5 illustrate a preferred embodiment of the presently disclosed intervertebral implant shown generally as 10. Briefly, implant 10 includes an upper surface 12, a lower surface 14 and a sidewall 15 positioned between the upper and lower surfaces. Upper and lower surfaces 12 and 14 each include a series of circular steps 16 which move upwardly from the outer periphery 18 of implant 10 to the center 20 of implant 10. Alternately, steps 16 need not be centered about the center of implant 10 nor do adjacent steps need be of the same height. A throughbore 22 extends between upper and lower surfaces 12 and 14 of implant 10. Throughbore 22 is dimensioned to receive growth factors including autograft, allograft, DBM, etc..., to stimulate bone growth.

FIGS. 6-10 also illustrate an implant 100 having stepped upper and lower surfaces 112 and 114. In contrast to the implant shown in FIGS. 1-5, implant 100 includes a greater number of steps 116 which define a more gradual taper than steps 16 of implant 10. It is envisioned that any number of steps may be provided on the upper and/or lower surfaces of the implant to provide any desired surface curvature. For example, each stop may have a height of from about .15mm to about 3mm. Other step dimensions are also envisioned.

FIG. 6A illustrates another alternate embodiment of the stepped implant shown in FIGS. 1-5 shown generally as 100'. Implant 100' includes a helical pathway 116' which extends from the outer periphery 118' of implant 100' towards the center of implant 100'. As discussed above, the helical pathway need not be centered about the central axis of implant 100' but rather it may be oriented to provide the desired curvature on the upper and/or lower surface of implant 100'. Moreover, the height of the step defined by the helical pathway 116' may vary along the length of pathway 116'.

Implants 10, 100 and 100' may be formed from a variety of different biologically compatible materials including ceramics, polymers, human or animal bone, carbon fiber tantalum composites, etc. using a variety of known processes including molding, casting, machining, etc. Preferably, implant 10 is formed from cadaveric human or animal bone by making a transverse cut through the diaphysis or metaphysis of a long bone, e.g., tibia, fibula, femur, ulna, radius, etc., to form a ring and thereafter machining the upper and/or lower surfaces of the implant, e.g., milling the stepped or helical configuration into the upper and lower surfaces of the ring. Alternately, only one of the upper and lower surfaces of the ring may be provided with a stepped configuration.

The bone used to form implants 10, 100 and 100' may be partially or fully demineralized bone. Preferably the bone is surface demineralized. By surface demineralizing the bone, the osteoconductivity and the conformability of the outer surfaces of the implant are improved while the strength of the inner portion of the implant is retained.

Referring to FIG. 11, implants 10, 100 and 100' may be positioned within a receiving bed formed between adjacent vertebrae 32 and 34. Because the upper and lower surfaces of the implants conform to the natural concavity of the vertebral endplates, only minimal preparation of the vertebrae is required by a surgeon prior to insertion of an implant to maintain the natural lordoses of the spine.

FIGS. 12-15 illustrate an alternate embodiment of the intervertebral implant shown generally as 200. Intervertebral implant 200 is preferably formed from a cortical ring allograft cut from the diaphysis or metaphysis of a long bone but may be formed from any biocompatible material having the requisite strength requirements. Implant 200 includes a tapered, ring-shaped body 212 having flat top and bottom surfaces 214 and 216, respectively. Anterior end 218 of

implant 200 has a height which is greater than the height of posterior end 220. The taper of the implant should be such as to conform to the vertebral end plates of adjacent vertebrae. Mating structure 222 for engaging corresponding structure of an insertion tool is formed in a sidewall 224 of implant 200 in the anterior end 218 of implant 200. A plurality of concentric rings 226 are formed in top and bottom surfaces 214 and 216. Rings 226 are preferably V-shaped, although other configurations are also envisioned, i.e., U-shaped, rectangular, etc. A throughbore 228 extends between top and bottom surfaces 214 and 216 of implant 200. If implant 200 is formed from bone, throughbore 228 may be defined by the intramedullary canal of the bone from which implant 200 is cut. Implant 200 is configured for anterior insertion into the intervertebral space. Growth factors including autograft, allograft, and demineralized bone particles may be positioned in throughbore 228 and/or rings 226 to stimulate bone growth.

FIGS. 16-19 illustrate an alternate embodiment of implant 200 shown generally as 300. Implant 300 is similar to implant 200 but includes convex top and bottom surfaces 314 and 316 which are configured to engage the vertebral end plates of adjacent vertebrae. Top and bottom surfaces 314 and 316 also include concentric rings 326 similar to those described above with respect to implant 200.

FIGS. 20-23 illustrate another alternate embodiment of implant 200 shown generally as 400. Implant 400 is similar to implant 200 except that anterior end 418 is approximately equal to the height of posterior end 420.

FIG. 24 illustrates a partially threaded stepped implant shown generally as 500. Implant 500 is preferably formed from cortical bone by making a transverse cut through the diaphysis or metaphysis of a long bone to obtain a cylindrical bone plug and thereafter machining and threading the bone plug. Alternately, implant 500 may be formed from any biocompatible

material having the requisite strength requirements using any known process including machining, molding, etc. Implant 500 includes a cylindrical body 510 having a first end portion 512 having a first outer diameter and a second end portion 513 having a second outer diameter larger than the first diameter. A variety of different diameter implants are envisioned. A throughbore 514 extends through first end portion 512 of cylindrical body 510. First end portion 512 has screw threads 516 at one end thereof, but does not include threads in the area about throughbore 514. Second end portion 513 includes screw threads 518. When implant 500 is formed by cutting a bone plug from a long bone, the absence of screw threads in the area of throughbore 514 facilitates the use of long bones having a thinner wall section, i.e.., the bone wall between the intramedullary canal of a long bone and the outer surface of the bone plug cut therefrom can be thinner.

When implant 500 is inserted into intervertebral space between adjacent vertebrae, second end portion 513 will sit in the vertebral wall and provide the majority of the retaining force. First end portion 512 will also screw into adjacent endplates but thread engagement may be minimal, especially if the intervertebral space is very concave. A stepped reamer and tap can be used to prepare the intervertebral space.

FIGS. 25 and 26 illustrate an alternate embodiment of implant 500 shown generally as 600. Implant 600 is similar to implant 500 except that second end 613 of implant 600 is tapered from one end to the other. Implant 600 may be used to vary the spine geometry. Referring to FIG. 26, during insertion of implant 600 into the intervertebral space, implant 600 will directly force adjacent vertebral surfaces 630 and 632 apart. The particular taper of second end portion 613 of implant 600 can be chosen to provide the desired spacing of the adjacent vertebrae.

Intervertebral implants in the form of threaded, cylindrical dowels formed of bone,

specifically, human or animal cadaveric bone, are well known in the surgical arts. Typically, such implants are formed by making a transverse cut through the diaphysis or metaphysis of a long bone, i.e., the femur, tibia, fibula, ulna or radius, using a cylindrical drill bit. One problem associated with forming and using bone dowel implants is that anatomical limitations make it difficult to recover bone dowels having the desired length needed for intervertebral fusion procedures. This is especially true when performing procedures in the cervical region of the spine wherein small diameter dowels are required.

In order to compensate for anatomical limitations, a dowel extender portion may be provided. Referring to FIGS. 27 and 28, a cylindrical dowel extender 710 may be implanted within the intervertebral space prior to implantation of the main dowel portion D (FIG. 27), or alternately, after implantation of main dowel portion D (FIG. 28). Preferably, dowel extender portion 710 includes helical threads 712 to engage vertebral end plates 714 and 716 and retain the dowel extender portion in place. However, non-threaded dowel extender portions are also envisioned. Each dowel extender portion 710 preferably includes engagement structure, such as slot 718, for engaging an insertion tool (not shown).

Generally, dowel extenders having a length of from about 4 to 8mm are needed to supplement the main dowel, although other length dowel extenders may also be needed depending upon the particular surgical procedure being performed. A common thread pattern associated with intervertebral dowels is 10 threads per inch. Thus, a dowel extender having a length of 4mm will only have about 1.57 threads and a dowel extender having a length of 6mm will have only about 2.35 threads. Because of the limited number of threads and the short thread engagement length, it may be difficult to stabilize a dowel extender in the intervertebral space and problems may result. For example, if the dowel extender is not firmly seated in the intervertebral space

between adjoining vertebrae when contacted by the main dowel, it may tip over.

In order to provide greater stability, an alternate embodiment of the presently disclosed dowel extender is described herein. Referring to FIGS. 29 and 30, dowel extender 800 includes a cylindrical body 810 having a first end 812 and a second end 814. Second end 814 includes a projection 816 configured and dimensioned to be received within a correspondingly shaped slot formed on one end of main dowel D. Although illustrated as having a dove-tail configuration, projection 816 may assume other configurations capable of interlocking with a correspondingly shaped slot. Referring to FIG. 29, locking pins 820 may be provided to further secure dowel extender portion 800 to main dowel portion D. Alternately, a locking pin or pins may be used to entirely replace projection 816 and secure dowel extender 800 to main dowel D.

In an alternate embodiment, a bone dowel is constructed from multiple dowel segments which are secured together using interlocking structure. The interlocking structure may be formed integrally with each dowel segment, e.g., each dowel segment may have a slotted front end and a correspondingly shaped projection formed at a rear end. Each dowel segment has a predetermined length and is joined to one or more other dowel segments to form a dowel having a desired length. For example, dowel segments may be formed having lengths of 2, 4 and 6mm. In order to form a dowel having a length of 20mm, three 6mm dowel segments and a 2mm dowel segment can be joined together. The dowel segments are preferably formed from bone, although other biocompatible materials listed above are also envisioned. The dowel segments may be cylindrical, rectangular, wedge-shaped, etc. For example, FIG. 31 illustrates a wedge shaped intervertebral implant 900 formed of multiple implant segments 910 which are fastened together in the manner described above.

It will be understood that various modifications may be made to the embodiments

disclosed herein. For example, the configuration of the sidewall of any of the implants described above may be modified to better suit a particular procedure, i.e., the sidewalls can be formed to be rectangular, circular, triangular, semi-circular, etc. Moreover, the implants described above, although disclosed in the context of spinal implantation, may be suitable for other implantation procedures not specifically listed here but obvious to those of ordinary skill in the art. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

CLAIMS:

1. An intervertebral implant comprising:

a first implant portion having a first end and a second end, the second end having engaging structure formed therein;

a second implant portion having a first end and a second end, the first end of the second implant portion including engaging structure formed thereon, the engaging structure formed on the first end of the second implant portion being configured to mate with the engaging structure formed on the second end of the first implant portion to fasten the second implant portion to the first implant portion.

2. An intervertebral implant according to Claim 1, wherein one of the first and second engaging structures includes a dovetail connector.

3. An intervertebral implant according to Claim 1, wherein the first and second implant portions are cylindrical.

4. An intervertebral implant according to Claim 1, wherein the first and second implant portions are wedge-shaped.

5. An intervertebral implant according to Claim 1, further including at least one pin extending between the first and second implant portions.

6. An intervertebral implant according to Claim 2, wherein the other of the first and

second engaging structures includes a slot configured to receive the dovetail connector.

7. An intervertebral implant according to Claim 1 further including a third implant portion having first and second ends and third engaging structure.

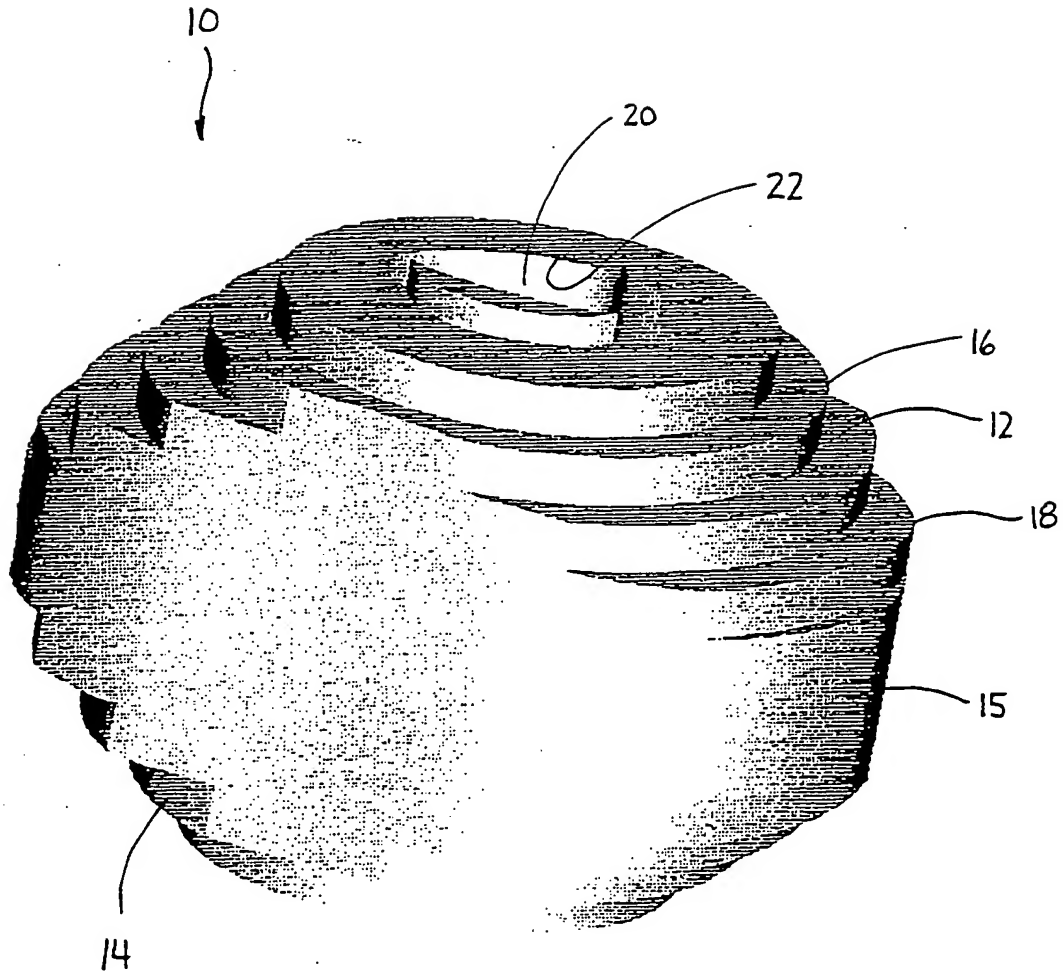

FIG. 1

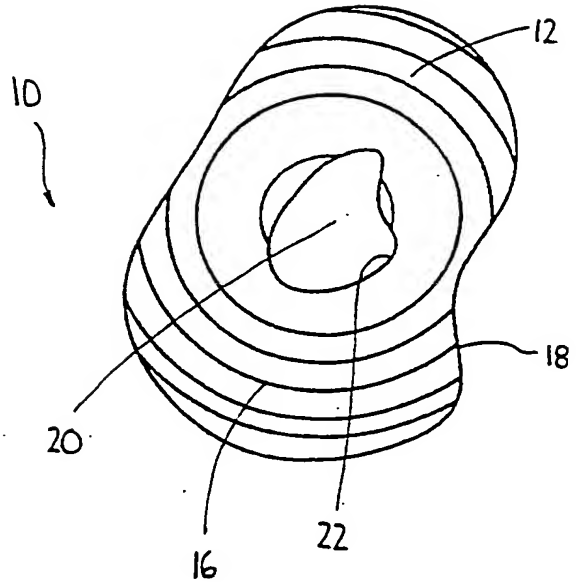

FIG. 2

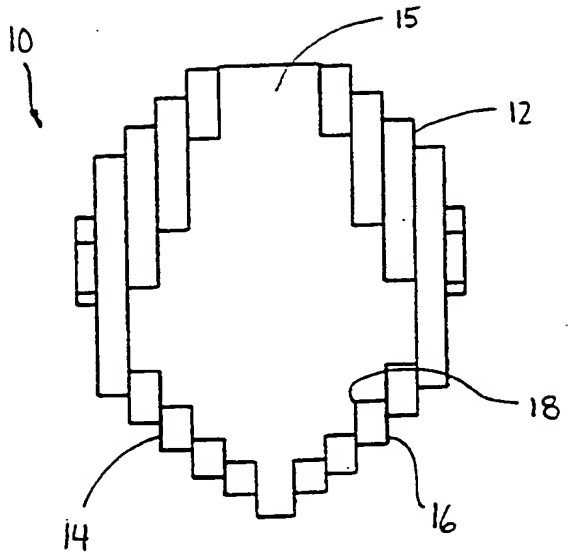

FIG. 3

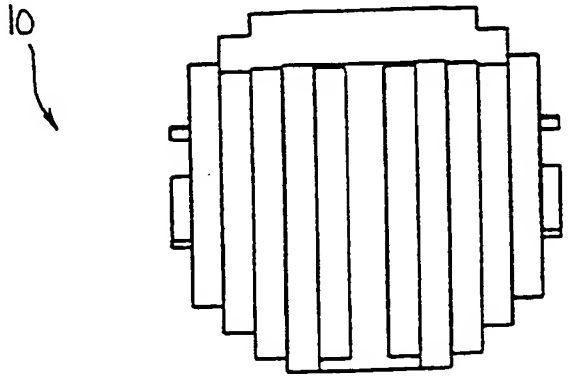

FIG. 5

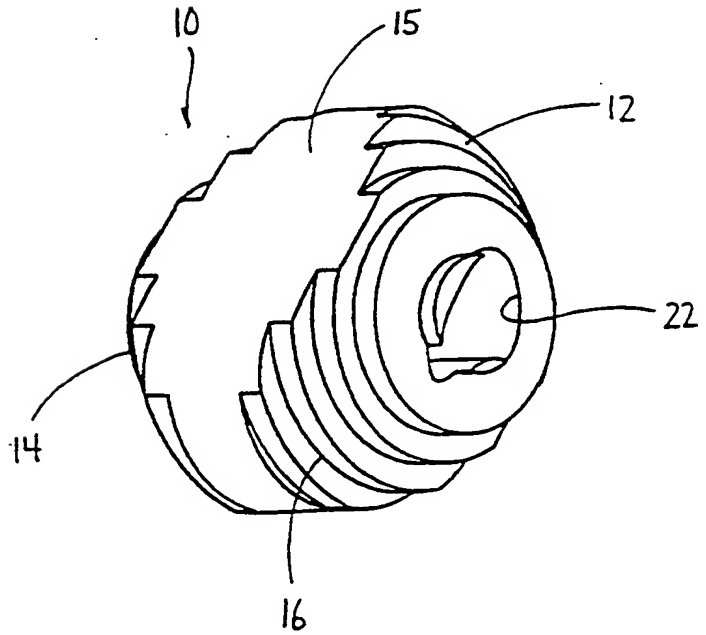

FIG. 4

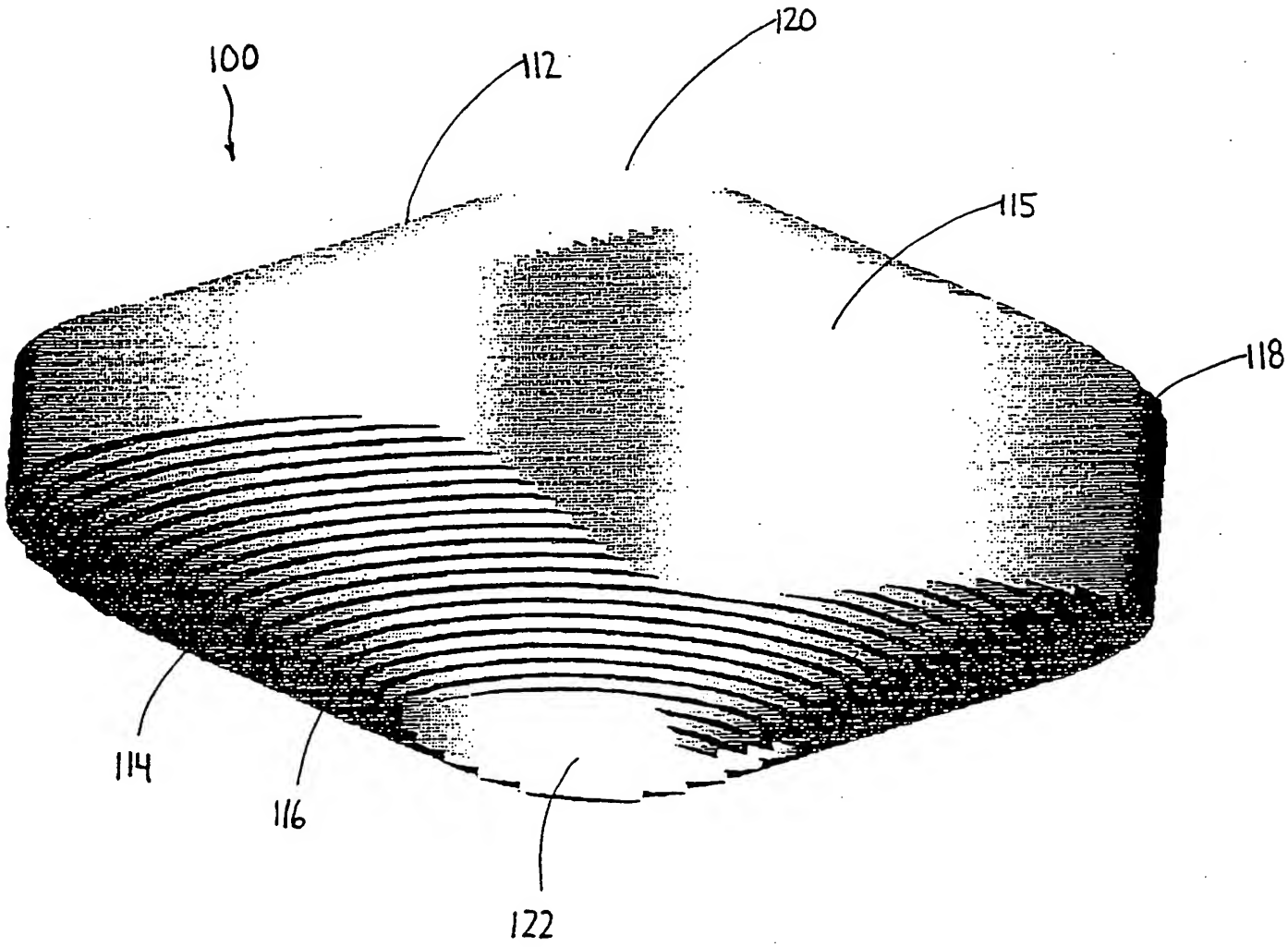

FIG. 6

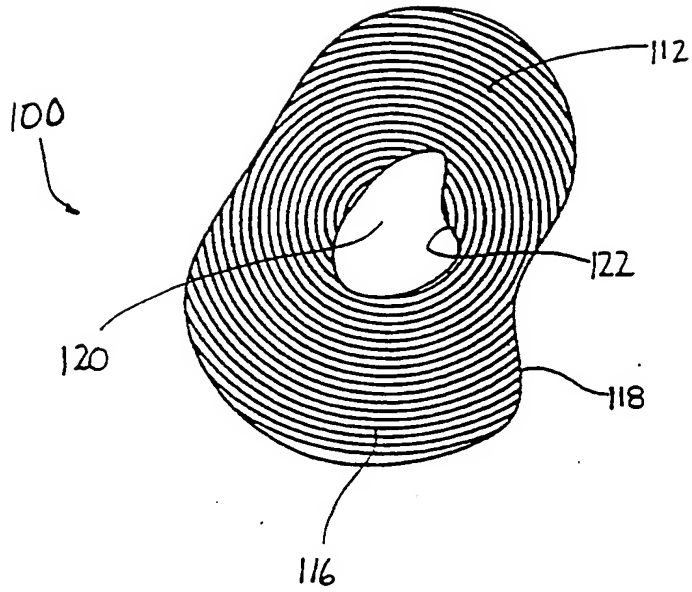

FIG. 7

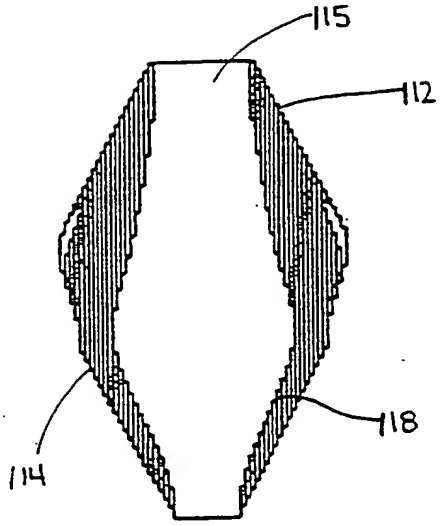

FIG. 8

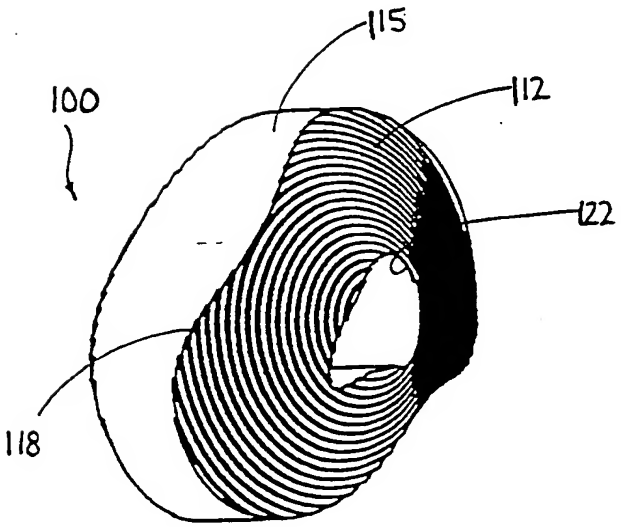

FIG. 9

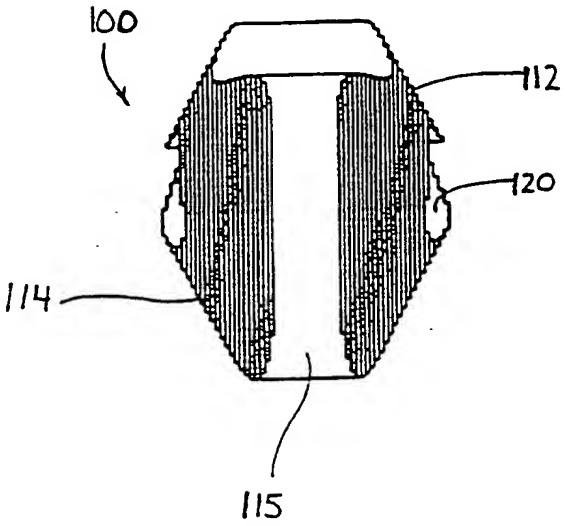

FIG. 10

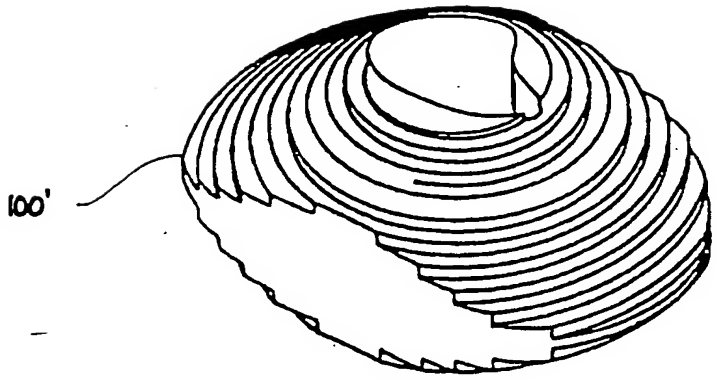

FIG. 6A

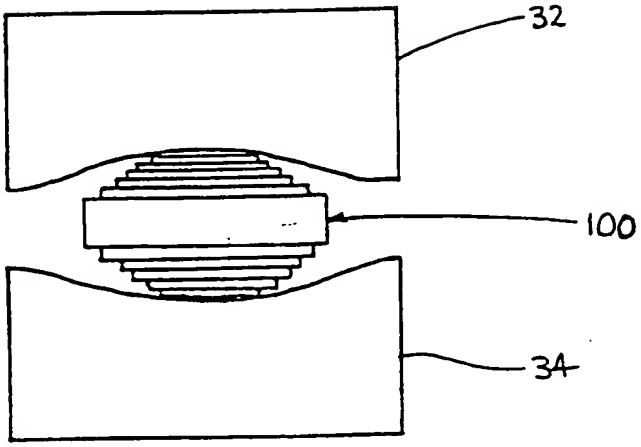

FIG. 11

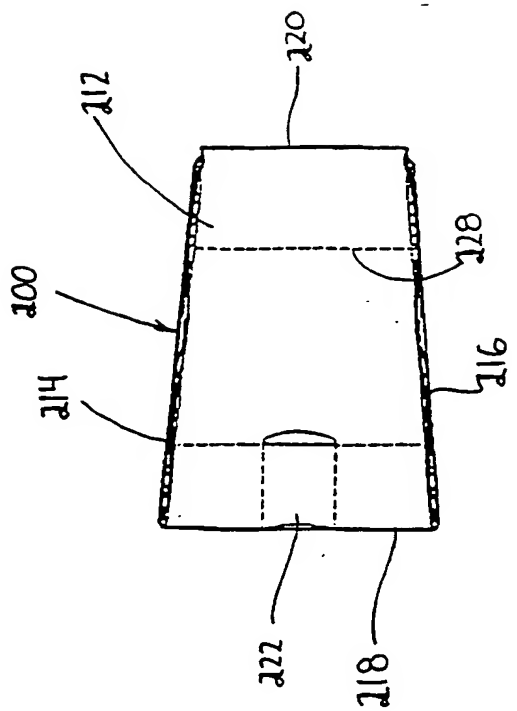

FIG. 13

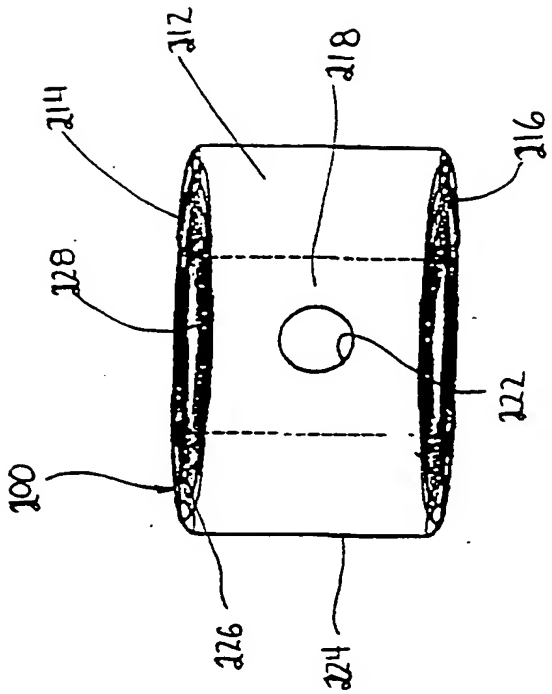

FIG. 15

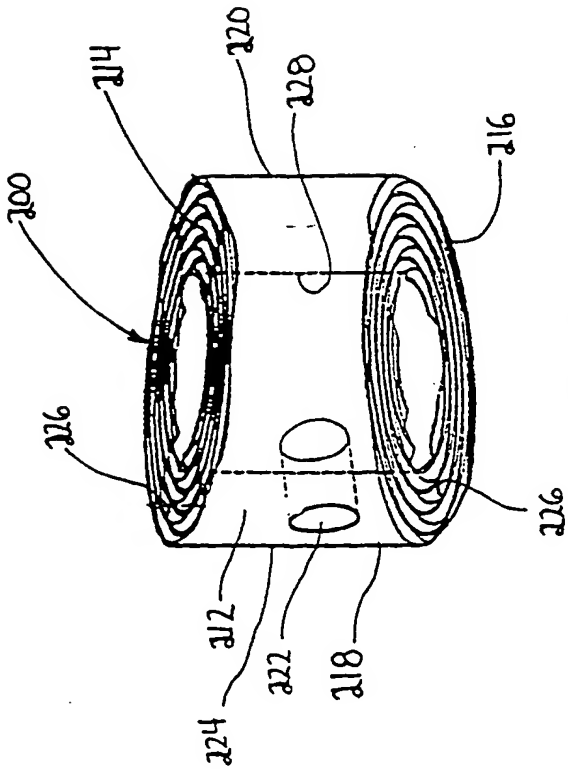

FIG. 12

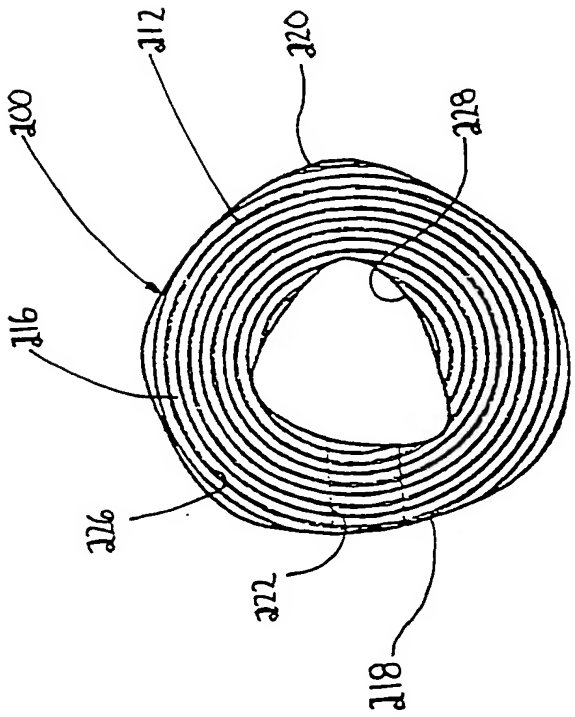

FIG. 14

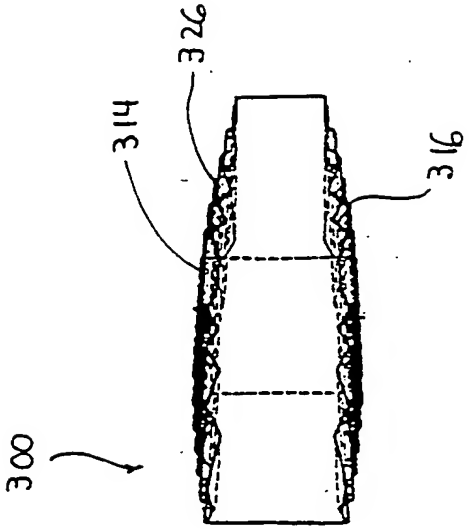

FIG. 17

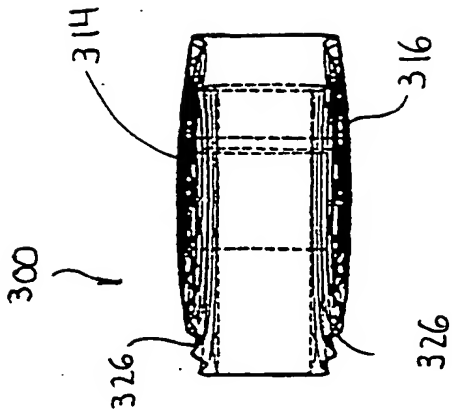

FIG. 19

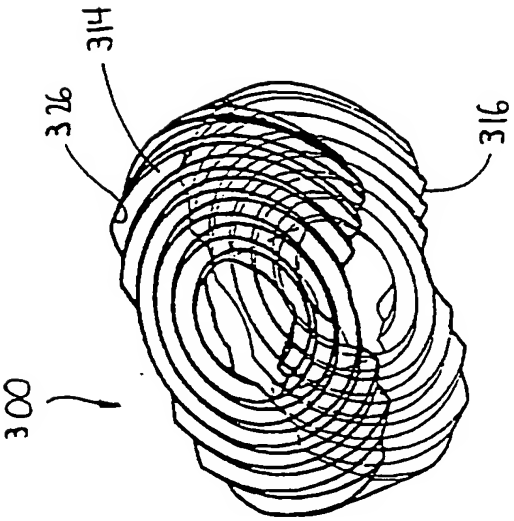

FIG. 16

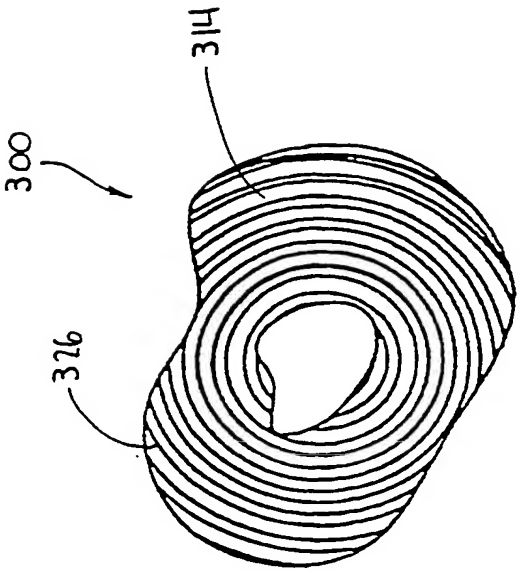

FIG. 18

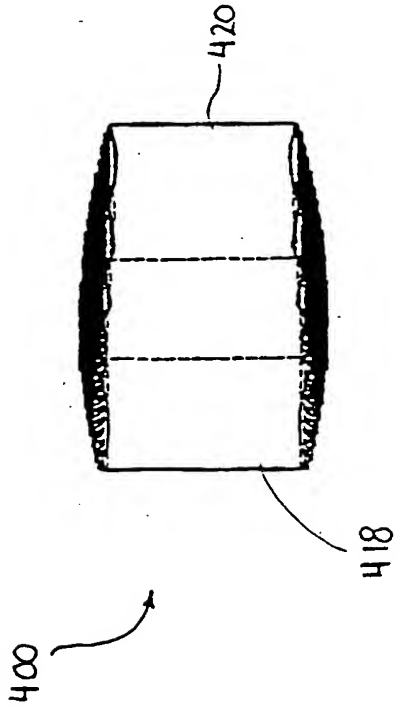

FIG. 21

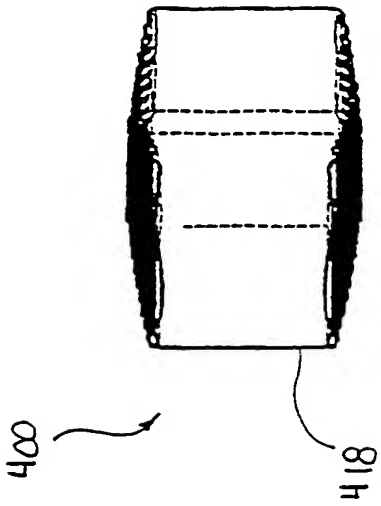

FIG. 23

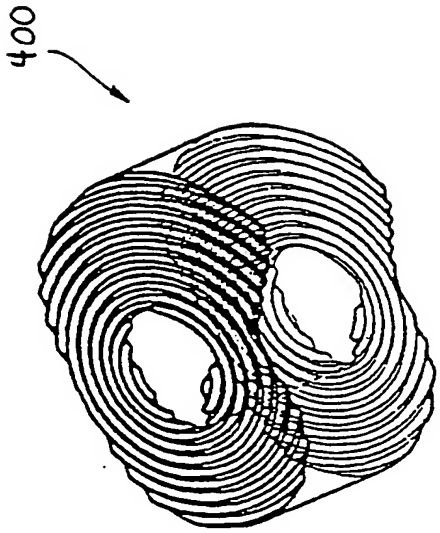

FIG. 20

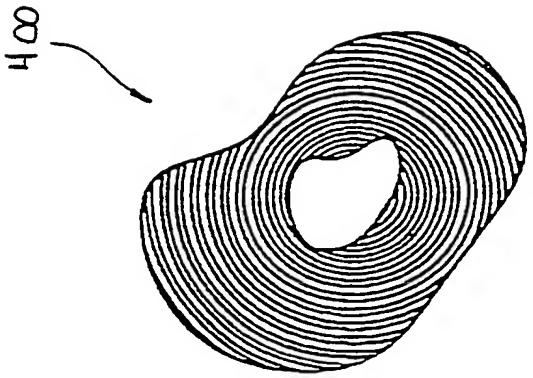

FIG. 22

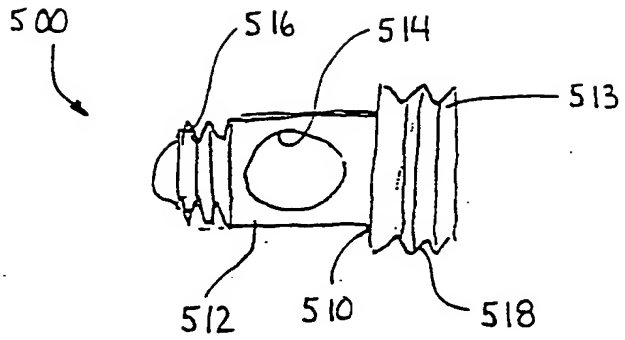

FIG. 24

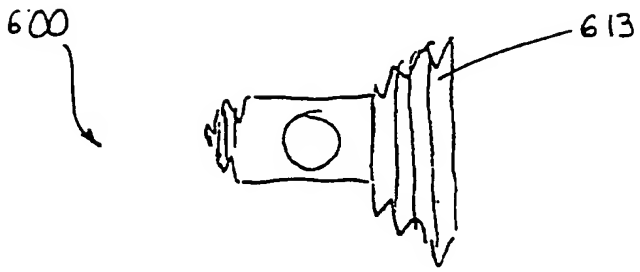

FIG. 25

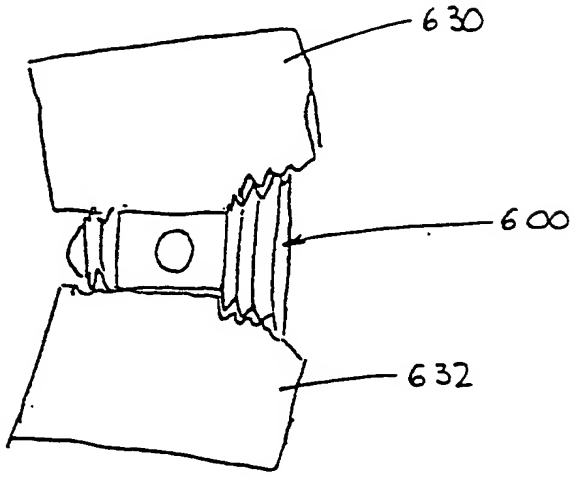

FIG. 26

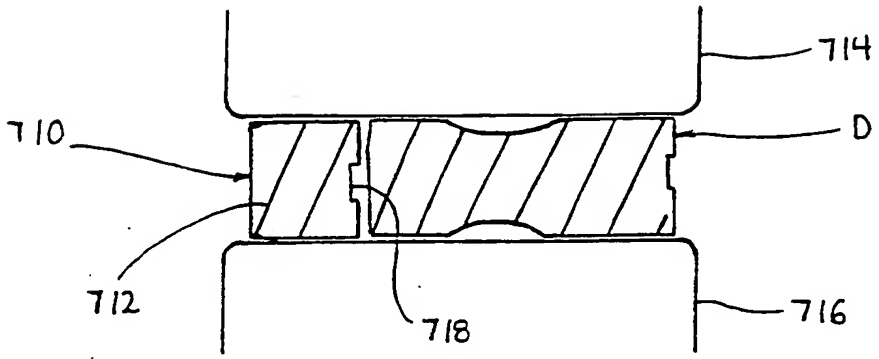

FIG. 27

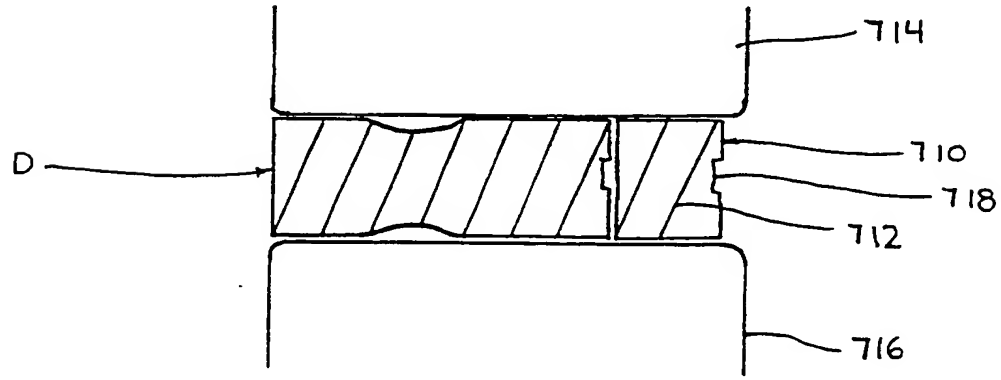

FIG. 28

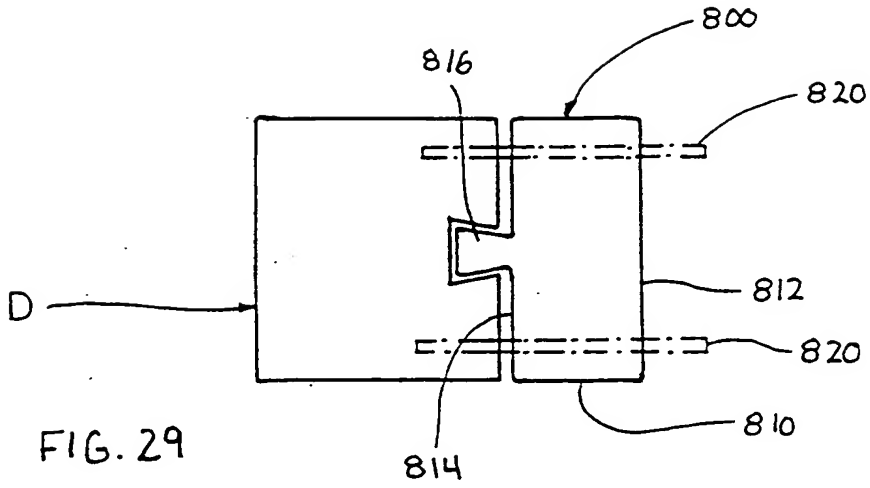

FIG. 29

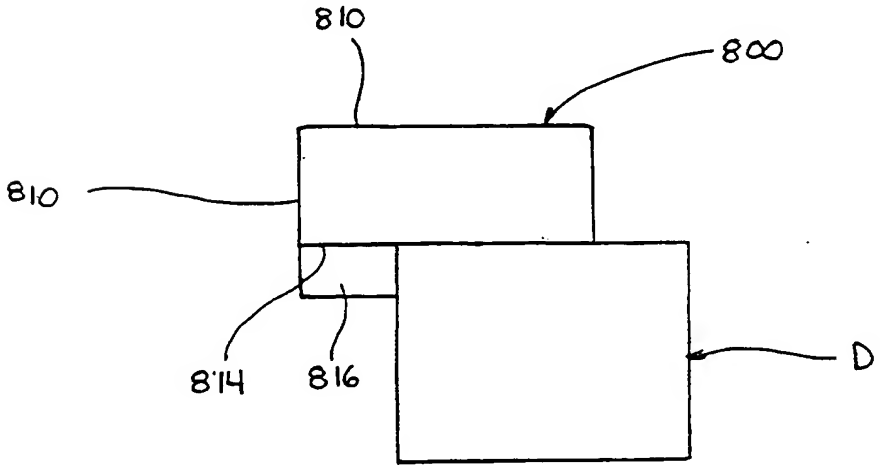

FIG. 30

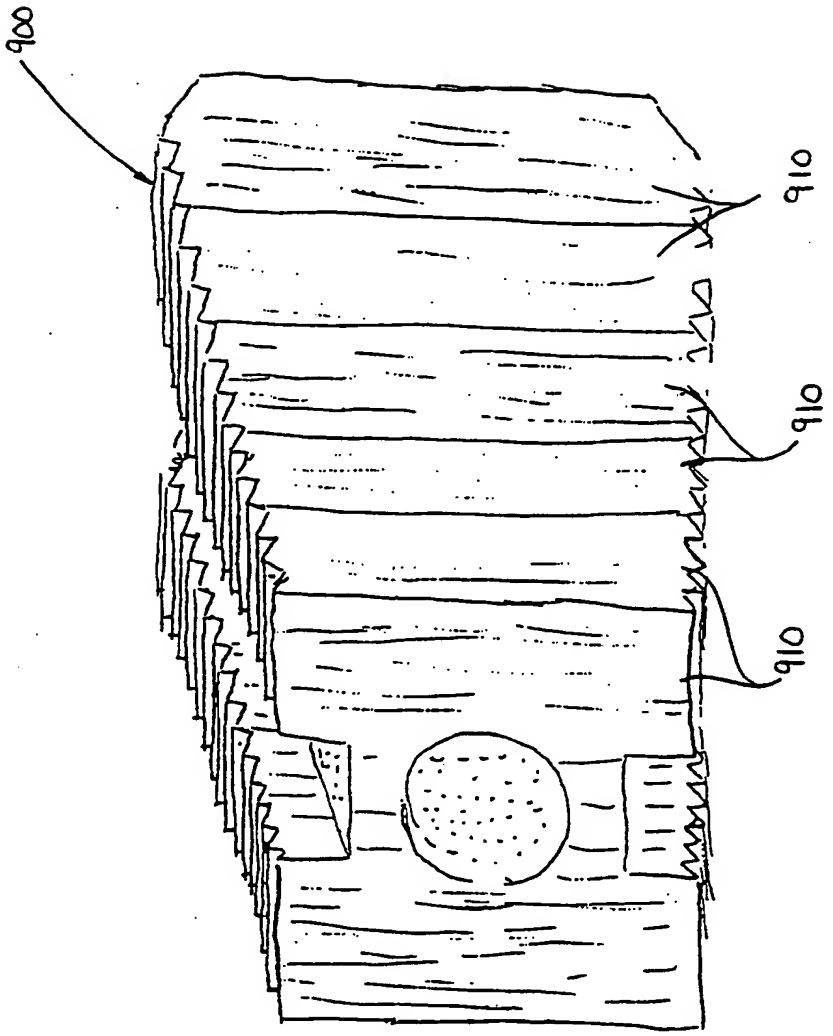

FIG. 31

INTERNATIONAL SEARCH REPORT

Intern. nal Application No
PCT/US 01/00112

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 397 364 A (KOZAK JEFFREY ET AL) 14 March 1995 (1995-03-14) figures 4-16,21,26,27 column 6, line 60 -column 7, line 62 column 11, line 36 - line 52	1,2,4,6, 7
A	---	5
X	DE 298 14 174 U (HOWMEDICA GMBH) 16 December 1999 (1999-12-16) figures 1-3 page 8	1,2,5-7
Y	---	3
X	DE 40 12 622 C (ESKA MEDICAL) 18 July 1991 (1991-07-18) column 5, line 2 - line 9; figures 1,2	1,5
A	---	2,6
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
5 April 2001	18/04/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

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INTERNATIONAL SEARCH REPORT

Intern. nal Application No
PCT/US 01/00112

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No
Y	WO 97 47258 A (ULRICH HEINRICH ;SCHOENHOEFFER HELMUT (DE)) 18 December 1997 (1997-12-18) figures 2,4,8 page 7, line 13 - line 23	3
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A	EP 0 325 566 A (SALUS SRL ;UGOLINI FILIPPO (IT)) 26 July 1989 (1989-07-26) figures 1,5 column 3, line 51 - line 60	1,2,5-7
P,X	--- WO 00 07527 A (SYNTHES AG ;SYNTHES USA (US)) 17 February 2000 (2000-02-17) abstract; figures 2,7,9,11	1,4,5,7
P,X	--- WO 00 40177 A (LIFENET) 13 July 2000 (2000-07-13) abstract; figures 41,42C	1,2,4-7
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Interr. nal Application No
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